

## **REMARKS**

Applicants have the following comments in response to the Office Action of July 26, 2006.

### **I. Claim Amendments – Reference to Disclosure**

As explained in depth below, while Applicants respectfully traverse the rejection in the Office Action, in order to advance the prosecution of this application, independent Claims 17 and 32 have been amended. The amended claims are explicitly directed to methods for treating diseased tissue and for use of certain topically-applicable photodynamic pharmaceutical compositions or medicaments.

#### **Claimed Concentration Range**

Applicants have amended the independent claims to recite that the concentration of the active component (i.e., the halogenated xanthene) is within the range of approximately 1 micromolar to approximately 10 micromolar. This claimed range of halogenated xanthene concentration is shown, for example, on page 18, lns. 13-15 of the specification which discloses use of an example halogenated xanthene compound Rose Bengal “at a concentration of approximately 1 to 10 micromolar or greater.” Thus, the claimed concentration range is supported by and encompassed within the examples in the present application.

#### **Application to Tissue**

Applicants have also amended the independent claims to recite that the claimed compositions and medicaments are applied to diseased tissue. Such application is consistent with each of

Applicants' example embodiments, including the:

second example (page 12, ln. 18 - page 13, ln.18, which discloses applying the medicament to tissues to be treated at page 12, lines 20-21 and a specific example of the composition being applied to persistent leg ulcers);

third example (page 13, ln. 22 - page 14, ln.21, which discloses applying the medicament to tissues to be treated at page 13, line 24 - page 14, line 2 and a specific example of the composition being applied to esophageal tissue);

fourth example (page 15, ln. 2 - page 16, ln.4, which discloses applying the medicament to tissues to be treated at page 15, lines 6-8 and a specific example of the composition being applied to diseased tissue such as of bladder tumors);

fifth example (page 16, lns. 8 - 24, which discloses applying the medicament to tissues to be treated at page 16, lines 10-11 and a specific example of the composition being applied to diseased tissue such as of tracheal tumors);

sixth example (page 17, lns. 4 - 24, which discloses applying the medicament to tissues to be treated at page 17, lines 3-8 and a specific example of the composition being applied to breast adenocarcinoma and sarcoid tissues); and

seventh example (page 18, lns. 3 - 24, which discloses applying the medicament to tissues to be treated at page 18, lines 5-6 and a specific example of the composition being applied to infectious organisms).

Thus, the claimed method and use of applying the pharmaceutical composition or medicament to tissue of independent Claims 17 and 32 is supported by and encompassed within these examples in the specification of the present application.

### Activation after Latency Period

Each of the aforementioned example embodiments are predicated on illumination of the treated tissue after a latency period (i.e., interval between application and activation) of 0-72 hours, and more preferably 0-1 hour, with continuous or pulsed light in the 500-600 nm band (see, for example, page 13, lns. 10-12; page 14, lns. 13-15; page 15, lns. 21-23; page 16, lns. 16-18; page 17, lns. 16-18; and page 18, lns. 17-19). Applicants have amended the independent claims to clearly recite the latency period of 0-1 hour prior to application of activating light. Thus, this claimed detail of independent Claims 17 and 32 is supported by and encompassed within these examples in the present application.

Accordingly, such amendments do not add any new matter and are clearly supported by the application as filed. Therefore, it is respectfully requested that each of these amendments be entered and allowed.

Applicants will now address the Examiner's sole rejection in the Office Action.

## **II. Claim Rejections – 35 USC §112**

In the Office Action, the Examiner rejects Claims 17-19 and 32-34 under 35 USC §112, first paragraph, for alleged failure to comply with the written description requirement. This rejection is respectfully traversed.

While Applicants traverse this rejection, in order to advance the prosecution of this application, Applicants are amending Claims 17 and 32, as discussed *supra*.

More specifically, the Examiner appears to object to the recitation of each of the claimed features in combination in the claimed method or use. Applicants have explained *supra* that there is clear support for each of these claimed features, as amended, in combination in the various examples in the specification. Further, at the bottom of page 17, for example, the specification states that the invention is not limited to the preferred embodiment but other formulations of halogenated xanthenes as described in the application can also be used for the specific indications described in the specification. This is sufficient disclosure for one skilled in the art.

In addition, the Examiner objects to the recital of “proximate” to the tissue to be treated. This term has been deleted and the claimed application is to tissue as described *supra*.

The Examiner also objects to the recital of a concentration range of greater than approximately 1 micromolar to less than approximately 0.1% w/v. Independent Claims 17 and 32 have been amended to recite a concentration range of approximately 1 micromolar to approximately 10 micromolar. As described *supra*, this feature is clearly supported by the specification.

It is respectfully submitted that such amendment overcomes the Examiner’s stated basis for this rejection. Accordingly, it is respectfully requested that this rejection be withdrawn.

### **III. Conclusion**

For at least the above-stated reasons, it is respectfully submitted that the claims of the present application are in an allowable form and are patentable. Accordingly, it is requested that the application be allowed.

If any further fee should be due for this amendment or extension of time, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

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